UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,572	11/30/2007	Gregory M. Lanza	532512001400	8304

25225 7590 09/21/2009

MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
SHOMER, ISAAC	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
09/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,572	LANZA ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claims 1-10, drawn to a method to deliver a desired agent selectively to a target.

II. Group II, claims 11-21, drawn to a formulation comprising an active composition and an inactive carrier.

III. Group III, claims 22-23, drawn to a method to obtain an ultrasound image.

IV. Group IV, claims 24-25, drawn to a method to obtain a proton magnetic resonance image.

V. Group V, claims 26-27, drawn to a method to obtain an optical image.

VI. Group VI, claims 28-29, drawn to a method to obtain an x-ray image.

VII. Group VII, claims 30-31, drawn to a method to obtain a F-19 magnetic resonance image.

As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so

linked as to form a single general inventive concept." Moreover, as stated in PCT Rule 13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group II is a formulation comprising an active composition of targeted vehicles and an active agent, as well as an inactive composition. The formulation of claim 11 does not present a contribution over the prior art.

Ahmad et al. (Cancer Research 53, April 1, 1993, pp. 1484-1488) (hereafter referred to as Ahmad) teaches a liposomal composition comprising doxorubicin, a monoclonal antibody (mAb), and the lipids abbreviated as HSPC, CH, and PEG-DSPE, as of Ahmad, page 1484 right column, section entitled "Liposome Preparation." That doxorubicin is an anticancer drug is shown by Ahmad, page 1484, left column, first lines of introduction section. That the mAb is a targeting agent to cancer cells is shown by

Ahmad, page 1484, left column, last paragraph. HSPC is hydrogenated soy phosphatidylcholine, CH is cholesterol, and PEG-DSPE is polyethylene glycol covalently coupled to distearoylphosphatidylethanolamine, as of Ahmad, page 1484 left column, last footnote.

The mAb and doxorubicin are considered to be the active composition of part (1) of claim 11, and the lipids are the inactive carrier of part (2) of claim 11. Hence, the formulation of claim 11 is not novel.

As such, Group II does not share a special technical feature with the instant claims of Group I and II-VII. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-VII is broken.

Election of Species

This application contains claims directed to more than one species of the generic invention. EACH of the following pecies are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows:

1. *Vehicle Type:* Applicant must elect a specific vehicle type or mixture of vehicle types (e.g. liposomes, bubbles containing gas, solid nanoparticles etc.). Applicant may elect distinct vehicle types for the active composition (1) and the inactive carrier (2) if

this is commensurate in scope with other elections. Claims 4, 15, 23, and 31 read on this species.

2. Vehicle Composition: Applicant must elect whether the vehicles in the carrier (2) and the composition (1) are of the same composition or not of the same composition. Claims 5-7 and 16-18 read on this species.

3. *Active Agent:* Applicant must elect a specific active agent. Claims 8 and 19 read on this species.

4. *Binding Moiety*: Applicant must elect a specific binding moiety (e.g. antibody, peptidomimetic). Claims 9 and 20 read on this species.

5. *Binding Target:* Applicant must elect a specific binding target (e.g. alpha-V-beta-3). Claims 10, 21, and 25 read on this species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Upon Applicant's election of species, the result must provide a single chemical species and a single condition or disease to be treated or improved. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The following claim(s) are generic:

Claims 1-3 are generic as to Group I.

Claims 11-14 are generic as to Group II.

Claim 22 is generic as to Group III.

Claim 24 is generic as to Group IV.

Claim 26 is generic as to Group V.

Claim 28 is generic as to Group VI.

Claim 30 is generic as to Group VII.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features because each chemical species is a distinct chemical which lacks a special technical feature in view of Ahmad et al. (Cancer Research 53, April 1, 1993, pp. 1484-1488).

Ahmad et al. (hereafter referred to as Ahmad) teaches a liposomal composition comprising doxorubicin, a monoclonal antibody (mAb), and the lipids abbreviated as HSPC, CH, and PEG-DSPE, as of Ahmad, page 1484 right column, section entitled "Liposome Preparation." That doxorubicin is an anticancer drug is shown by Ahmad,

page 1484, left column, first lines of introduction section. That the mAb is a targeting agent to cancer cells is shown by Ahmad, page 1484, left column, last paragraph. HSPC is hydrogenated soy phosphatidylcholine, CH is cholesterol, and PEG-DSPE is polyethylene glycol covalently coupled to distearoylphosphatidylethanolamine, as of Ahmad, page 1484 left column, last footnote.

The vehicle used as of Ahmad is a liposome, the active composition and inactive carrier are of the same composition, the active agent is doxorubicin, the binding moiety is an antibody, and the target is a cancer cell.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are

added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Joint Inventors and Rejoinder

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 1612

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642